6.0% for MACE, TVR, and TLR, respectively. The differences in absolute risk reduction were smaller in patients with ACS, but still in favor of SES.

ZES versus SES - 18 months clinical outcome						
	Acute Coronary Syndromes			Stable Angina Pectoris		
	ZES	SES	HR (95% CI)	ZES	SES	HR (95% CI)
N	506	546		614	592	
MACE	44 (8.7)	27 (5.0)	1.78 (1.10 - 2.88)	64 (10.4)	25 (4.2)	2.53 (1.60 - 4.02)
Death	20 (4.0)	14 (2.6)	1.55 (0.78 - 3.06)	25 (4.1)	15 (2.5)	1.61 (0.85 - 3.05)
Cardiac death	6 (1.2)	6 (1.1)	1.08 (0.35 - 3.36)	8 (1.3)	5 (0.8)	1.54 (0.50 - 4.72)
MI	15 (3.0)	7 (1.3)	2.34 (0.95 - 5.74)	8 (1.3)	4 (0.7)	1.94 (0.59 - 6.45)
ST	7 (1.4)	5 (0.9)	1.52 (0.48 - 4.78)	6 (1.0)	1 (0.2)	5.83 (0.70 - 48.4)
TVR	34 (6.8)	21 (3.9)	1.77 (1.03 - 3.04)	57 (9.3)	18 (3.1)	3.14 (1.85 - 5.34)
TLR	25 (5.0)	11 (2.0)	2.49 (1.23 - 5.06)	46 (7.5)	9 (1.5)	5.08 (2.49 - 10.4)
The numbers denote number of events and cumulative incidences						

Conclusion: ZES is inferior to SES. The differences between ZES and SES seem to be less pronounced in patients with acute coronary syndromes as compared to patients with stable angina pectoris.

TCT-255

Consistent Efficacy and Safety of Everolimus-Eluting Stents In 5054 Patients From a Large Prospective Real World Study: One-Year Clinical Outcomes From the XIENCE V® USA Study

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Background: The efficacy and safety of XIENCE V® everolimus-eluting coronary stents (XIENCE V, Abbott Vascular) have been demonstrated in the SPIRIT trials with low rates of TLR, MACE and stent thrombosis (ST). However, these results were obtained in a selected population. XIENCE V USA, a real-world study, provides more information on clinical outcomes with XIENCE V in more complex lesions.

Methods: XIENCE V USA is a prospective, multicenter, post-approval single-arm study designed to examine the safety and efficacy of XIENCE V in an all-inclusive, consecutively-enrolled population from real-world clinical settings. Patients were enrolled at the initiation of PCI with no inclusion/exclusion criteria beyond the use of only XIENCE V during the index procedure. Clinical endpoint events, including ST, cardiac death, MI, and revascularization, were adjudicated per ARC definitions by an independent Clinical Events Committee.
Results: A total of 5054 patients were enrolled in the study and 4958 patients reached 1 year for this analysis. Of these patients, ~36% were a standard-risk cohort, a non-complex population similar to SPIRIT IV, and 64% were a high-risk cohort, a complex population not studied previously in the randomized SPIRIT trials. At 1 year, the ARC-defined definite and probable ST rate was 0.86% for the overall population and 0.34% for the standard risk cohort. The TLR rate was 4.5% for the overall and 2.2% for the standard risk cohort. Target lesion failure (TLF: defined as cardiac death, ARC-defined MI attributed to the target vessel, and clinically indicated TLR) rate was 8.4% for overall and 4.6% for the standard risk cohort. Both ST and TLR rates of the standard risk cohort in XIENCE V USA were similar to the rates in the SPIRIT IV non-complex patients treated with XIENCE V (0.34% vs. 0.28% for ST, p=0.78; 2.2% vs. 2.7% for TLR, p=0.35).
Conclusion: In this large, real-world population, with a high proportion of complex patient and lesion subsets, XIENCE V demonstrated very low rates of ST, TLF, and TLR in both overall and standard risk cohorts. These 1-year clinical outcomes from XIENCE V USA confirm the safety and efficacy of XIENCE V in real world patients.

TCT-256

Effects Of Telmisartan On Endothelial Dysfunction After Coronary Drug-Eluting Stent Implantation In Hypertensive Patients

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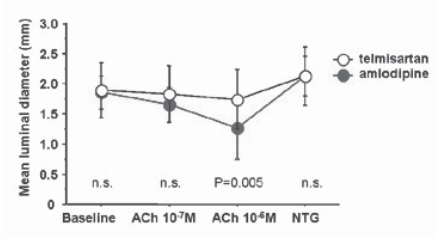
Background: Coronary drug-eluting stent (DES) implantation may impair local endothelial function. Telmisartan, an angiotensin II receptor blocker, has unique PPAR-gamma -mediated effects, and may have favorable effects on endothelial function. This prospective, randomized study was conducted to evaluate the effects of telmisartan on endothelial function after DES implantation in hypertensive patients, compared to a calcium channel blocker, amlodipine.
Methods: Forty hypertensive patients with coronary artery stenosis but without coronary artery spasm, treated with sirolimus-eluting stent, were randomly assigned to either telmisartan or amlodipine treatment group (telmisartan: 21 cases, amlodipine: 19 cases). After 3 months, endothelium-dependent and -independent vasomotion were evaluated with quantitative coronary angiography under the condition of withdrawal of medication. The mean diameter of a 20 mm coronary segment, starting 5 mm distal to the stent, were measured before and after intracoronary acetylcholine (ACh) infusion, and then after nitroglycerin (NTG) infusion.
Results: Blood pressure was comparable between groups at baseline and after 3 months. Mean luminal diameters at baseline, after intracoronary ACh infusion, and after intracoronary NTG infusion of the both groups are shown in the figure. Maximum vasoconstriction after ACh infusion was less pronounced in telmisartan group than in amlodipine group (-9.0 ± 9.6% vs -32.5 ± 24.3%, p=0.0002). There was no significant difference in endothelium-independent vasodilatation to NTG between groups (telmisartan: 12.6 ± 6.8%, amlodipine: 14.8 ± 5.4%, p=0.272).



Conclusion: Telmisartan would have favorable effects on endothelial dysfunction after DES implantation.

TCT-257

NEVO™ Sirolimus-eluting Coronary Stents Explanted from Porcine Models: Polymer Inlay Transition to Tissue

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Background: The NEVO™ Sirolimus-eluting Coronary Stent (SES) [Cordis Corporation, Bridgewater, NJ] utilizes unique RES TECHNOLOGY™, which incorporates hundreds of small reservoirs, each acting as a depot for drug delivery. The reservoir contains a bioabsorbable polymer inlay material consisting of poly (DL-lactic-*co*-glycolic acid) [PLGA] with the proven therapeutic agent sirolimus. The formulation was carefully designed to control the release of sirolimus in vivo. The erosion of polymer was designed for enhanced safety, to leave a bare metal stent.
Method: For this study, using spectroscopic techniques, we chemically characterized the material present within the reservoirs at fixed time points from implant in pigs through complete degradation of polymer. Specifically, we developed a quantitative confocal Raman spectroscopy method to visualize the spatial distribution of each of the components (drug, polymer, and other excipients) within the reservoir. A multivariate model was generated using experimental standards.
Results: At the early time points (day 1, 3, 5, 8, 14, 30), we observed the spatial drug distribution change luminally to abluminally as it eluted from the inlay. During the later points (day 60, 75, 90, and 180), when the majority of drug has been eluted, the material observed in the reservoir inlay transitions from polymer material to tissue. To confirm these findings, we developed chemical classification methods using Fourier Transform Infrared Spectroscopy (FTIR), PLS Discriminate analysis and Principal Component with SIMCA (soft independent modeling of class analogies) techniques to distinguish the NEVO™ SES inlay material from porcine tissue.
Conclusion: Confocal Raman spectroscopy quantitatively visualized the drug distribution from the NEVO™ SES inlay change over time. Using multivariate classification methods, we conclude that material in the inlays of the NEVO™ SES explants transition from active formulation to tissue. The samples examined trended from classification as NEVO™ SES formulation to tissue from day 1 to day 180 with the transition occurring at day 75 and complete about day 90.

TCT-258

Longest Available (up To Eight Years) Experience With Drug-eluting Stents For Non-selected Complex Patients: Assessing The Independent Predictors Of Negative Events In The Desire Registry

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Background: Although DES are markedly superior in reducing the need of repeat lesion revascularization when compared to BMS, the very long term outcomes of this novel technology remains relatively unclear, especially in more complex subsets of patients and lesions not initially investigated in controlled RCT.
Methods: The DESIRE registry is a prospective, single-center registry with consecutive patients treated solely with DES between May 2002 and Mar 2010. All subsets of patients and lesions are included in this registry. The primary goal was very long-term occurrence of MACE and stent thrombosis (ST). Patients were clinically evaluated at 1, 6 and 12 months and then annually, up to 8 years (ongoing FU). A multivariate model was built to determine independent predictors of MACE, TLR and ST.
Results: A total of 3,220 patients were included. The mean age was 64 ± 11 years. DM was detected in 28.6% and 44.8% presented with acute coronary syndrome. SVG lesions and STEMI pts represented 7% and 12% of the cohort, respectively. Cypher™ was the predominant DES (82.2%). Follow-up was obtained in 98% of the eligible patients (median 3.5 years). Up to seven-year follow-up, 89.6% of the population was free of any MACE. TLR was performed in 3.3% of the patients. Q-wave MI occurred in only 0.7% of these patients and total ST rate was 1.6% (n=42). Independent predictors of MACE were treatment of SVG lesions (HR 1,63; 95% CI, 1.22 to 2.18, p= 0.001), treatment of multivessel disease (HR 1.39; 95% CI, 1.03 to 1.87, p<0.001), residual stenosis (HR 1.3; 95% CI, 1.1 to 1.5, p= 0.034), DM (HR 1.6; 95% CI, 1.1 to 2.2, p= 0.006) and renal insufficiency (HR 1.5; 95% CI, 1.34 to 1.81, p= 0.004).Independent predictors of ST were PCI in the setting of STEMI (HR 3.5; 95% CI, 1.3 to 9.4, p= 0.013), stent length (HR 1.8; 95% CI, 1.09 to 3.02, p=0.023), moderate to severe calcification at lesion site (HR 2.38; 95% CI, 1.34 to 4.23, p=0.003), DM (HR 2.3; 95% CI, 1.8 to 4.7, p<0.001), and, in-stent residual stenosis (HR 1.04; 95% CI, 1.01 to 1.06, p=0.003).
Conclusion: The use of DES in unselected population was associated with very long-term sustained safety and effectiveness with acceptable low rates of adverse clinical events, including ST.

POSTER